PART 80—COLOR ADDITIVE CERTIFICATION

Subpart A—General Provisions

Subpart B—Certification Procedures

AUTHORITY: 21 U.S.C. 371, 379e.

SOURCE: 42 FR 15662, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (j)(2) shall be 30 cents per pound of the batch covered by such requests, but no such fee shall be less than $192.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (j)(4) shall be:

(1) 100 pounds or less—$30.

(2) Over 100 pounds but not over 1,000 pounds—$30 plus 6 cents for each pound over 100 pounds.

(3) Over 1,000 pounds—$84 plus 2 cents for each pound over 1,000 pounds.

(c) *Advance deposits.* Any person regularly requesting certification services may deposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Food and Drug Administration, collectable at par at Washington, DC. All such deposits and fees shall be forwarded to the Center for Food Safety and Applied Nutrition (HFS–100), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United States for deposit to the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

(e) *Refunds from advance deposits.* Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than $5.00.

[42 FR 15662, Mar. 22, 1977, as amended at 47 FR 24692, June 8, 1982; 54 FR 24890, June 12, 1989; 59 FR 60899, Nov. 29, 1994; 61 FR 3572, Feb. 1, 1996; 61 FR 14479, Apr. 2, 1996]

Subpart B—Certification Procedures

§ 80.21 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Commissioner of Food and Drugs.

(b) Be prepared in the manner set forth in paragraph (j) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.

(e) Show the name and post office address of the actual manufacturer in case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in § 80.10 unless the person has established with the Food and Drug Administration an advanced deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by § 80.10 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in § 80.22 consisting of:

(1) Four ounces in the case of straight colors and lakes.

(2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

(1) The name of a straight color shall be the name of the color as listed in parts 74 and 81 of this chapter.

(2) The name of a lake shall be the name derived in the manner described in part 82 of this chapter.

(3) The name of a mixture shall be the name given to such mixture by the person requesting certification.

(4) The name of a repack shall be the name described in paragraph (h)(1), (2), or (3) of this section, whichever is applicable.

(i) The information and samples enumerated in paragraphs (a) to (h), inclusive, of this section are the minimum required. Additional information and samples shall be submitted at the request of the Food and Drug Administration when such additional information and samples are necessary to determine compliance with the requirements of § 80.31 for the issuance of a certificate.

(j) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack of a previously certified color additive, or a color additive mixture.

(1) *Request for certification of a batch of straight color additive.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St., SW.,
Washington, DC 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color _____
(As listed in 21 CFR part 74)

Batch number _____
(Manufacturer's number)

Batch weighs _____ pounds
Batch manufactured by _____at _____(Name and address of actual manufacturer)

How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested of this color for use in _____
_____
_____
(State proposed uses)

Required fee, $——— (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(2) *Request for certification of a batch of color additive lake.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive lake.

Name of color _____
Batch number _____
(Manufacturer's number)

Batch weighs _____ pounds

Name of color used _____

Quantity _____ pounds

Lot number _____
(When certification of the lake for use in foods is requested)
Precipitant used _____
Substratum used _____

Quantity _____ pounds
Batch manufactured by _____at _____(Name and address of actual manufacturer)

How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested of this color for use in _____
_____
_____
(State proposed uses)

Required fee, $——— (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(3) *Request for certification of a repack of a batch of certified color additive.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive repack.

Name of color _____
(As listed in regulations and as certified; or repacker's name, if a mixture)
Original lot number _____
Certified color content _____
This color obtained from _____
Batch number _____

Batch weighs _____ pounds

How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in _____
_____
_____
(State proposed uses)

Required fee, $——— (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(4) *Request for certification of a batch of color additive mixture.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive mixture.

Name of mixture _____
(Manufacturer's trade name)
Batch number _____
(Manufacturer's number)

Weight of batch _____ pounds
Volume of batch _____ (If liquid) gallons

Batch manufactured by _____

Constituents of the mixture:
1. Color(s). (List separately each color and each lot number.)

Name of color as certified — Lot number
_____
_____
Quantity used (*in pounds*) — *Obtained from*
_____
_____

2. List of diluents. (List separately each diluent.)

Name of diluent
_____
_____

Quantity used

By weight — By volume (*if liquid*)
_____
_____

Batch mixed as follows _____
(Describe in detail)
How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in _____
_____

(State proposed uses)

Required fee, $——— (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) ———————

By ———————

———————

(Title)

[42 FR 15662, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979; 44 FR 22053, Apr. 13, 1979, as amended at 54 FR 24890, June 12, 1989; 61 FR 14479, Apr. 2, 1996]

§ 80.22 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

(a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.

(b) Held under the control of the person requesting certification until certified.

(c) Be labeled to show:

(1) The name of the color additive.

(2) The manufacturer's batch number.

(3) The quantity of such batch.

(4) The name and post-office address of the person requesting certification of such batch.

(5) Be accompanied by any label or labeling intended to be used.

§ 80.31 Certification.

(a) If the Commissioner determines, after such investigations as he considers to be necessary, that:

(1) A request submitted in accordance with §80.21 appears to contain no untrue statement of a material fact;

(2) Such color additive conforms to the specifications and any other conditions set forth therefor in parts 81 and 82 of this chapter.

(3) The batch covered by such request otherwise appears to comply with the regulations in this chapter, the Commissioner shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by part 74, 81, and 82 of this chapter, is a certified batch.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with §80.21, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating his reasons for refusal. Any person who contests such refusal shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

§ 80.32 Limitations of certificates.

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and a color additive from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever, the Commissioner learns that any certificate has been obtained through fraud or material misrepresentation, he shall notify the holder of the certificate that it is of no effect.

(b) If between the time a sample of color additive accompanying a request for certification is taken and the time a certificate covering the batch of such color additive is received by the person to whom it is issued, any such color additive becomes changed in composition, such certificates shall not be effective with respect to such changed color additive and such changed color additive shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(c) If at any time after a certificate is received by the person to whom it is issued any color additive from the batch covered by such certificate becomes changed in composition, such certificate shall expire with respect to such changed color additive. After such expiration, such color additive shall be considered to be from a batch that has not been certified in accordance with